

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Examiner: Humera N. Sheikh

Steven Z. Wu et al.

Serial No.: 10/663,568

Art Unit: 1615

Filed: September 15, 2003

Title: Microparticle Coated Medical Device

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, Virginia 22313-1450

RESPONSE TO OFFICE ACTION

Dear Examiner Sheikh:

This is a Response to the Office Action mailed on December 19, 2007.

In the Claims

Claims 1-24 (Canceled).

25. (Currently amended) A drug loaded stent, comprising:

a radially expandable stent body,

a coating layer disposed on the stent body, and

polymeric particles containing a therapeutic substance embedded within the coating layer, wherein the coating layer comprises a polymer different than the polymer from which the particles are made.

26. (Cancelled)

27. (Previously presented) The stent of Claim 25, wherein the coating layer is free from any therapeutic substances.

28. (Previously presented) The stent of Claim 25, wherein the polymeric particles are made from a hydrogel material.

29. (Previously presented) The stent of Claim 25, wherein the particles are 0.5 to 2 microns in size.

30. (Previously presented) The stent of Claim 25, wherein the therapeutic substance is for the treatment of restenosis.

31. (Previously presented) The stent of Claim 25, wherein the therapeutic substance is a radioactive isotope.

32. (Currently Amended) A medical device, comprising an implantable substrate and a coating, wherein the coating is free from any therapeutic substances but includes particles of a polymeric material having a therapeutic substance added thereto.

33. (Cancelled)

REMARKS

Claims 25 and 27-32 are pending. Claims 1-24, 26 and 33 have been cancelled. Claims 25 and 32 have been amended. No new matter has been added by the amendment.

Claim Rejections under 35 U.S.C. § 102(e)

Claims 25, 28-30 and 32 have been rejected under 35 U.S.C. § 102(e) as anticipated by U.S. Patent No. 6,719,998 to Golomb et al. Golomb discloses pharmaceutical-containing nanoparticle compositions for the prevention or treatment of restenosis. Golomb further discloses coating these compositions onto a stent. It is the position of the Examiner that Golomb teaches the invention as presently claimed and that the stent of the present application is inherent given the disclosure of Golomb. Applicants respectfully disagree.

Applicants' Response

With respect of claim 25, nowhere does Golomb disclose, either expressly or inherently, drug-containing polymeric particles embedded within a coating layer on a stent. Golomb, rather, simply mentions the use of "...liquid carriers known in the art..." (Col. 6, lines 25-27) and that these carriers, i.e., drug delivery systems, can be coated on a stent. (Col. 6, lines 51-54). There is no mention or suggestion that the liquid carriers are embedded within a distinct coating layer on a stent. Rather, the liquid carriers of Golomb act as the coating layer itself.

Second, nowhere does Golomb disclose, either expressly or inherently, that the coating layer includes an additional "...polymer different than the polymer from which the particles are made", as recited in claim 25. Golomb merely mentions that a drug delivery system, i.e., liquid carrier, can be coated on a stent. There is no indication that an additional different polymer is present in the stent coating.

Third, inherency requires that a cited reference "...may anticipate without disclosing a feature of the claimed invention if that characteristic is necessarily present, or inherent, in the single anticipating reference." *The Toro Company v. Deere & Company*, 355 F.3d 1313 (Fed. Cir. 2004), citing *Schering Corp. v. Geneva Pharmaceuticals, Inc.*, 339 F.3d 1373 (Fed. Cir. 2003). Golomb only discloses the

coating of a drug delivery system, i.e., polymer particle containing a therapeutic substance, onto a stent. (Col. 6, lines 51-54). There is no indication, nor even suggestion, that an additional polymer separate from the polymer from which the delivery system is made must necessarily be present in the coating layer.

Furthermore, inherency "may not be established by probabilities or possibilities. The mere fact that a certain thing may result from a given set of circumstances is not sufficient." *SmithKline Beecham Corporation v. Apotex Corporation*, 03-1285 (Fed. Cir. 2005). There is no indication in Golomb that an additional polymer, separate from the delivery system polymer, is present or even that one might be present. Indeed, assuming the disclosures of Golomb are enabling, the coating of Golomb is quite self-contained and would not need additional polymers to function.

With respect of claim 32, nowhere does Golomb disclose, either expressly or inherently, a device coating free from any therapeutic substances but including particles of a polymeric material having a therapeutic substance added thereto. Golomb, rather, discloses drug delivery systems, e.g., drug-loaded liposomes, that are coated on a stent. (Col. 6, lines 5-7 and 51-54). There is no mention or suggestion that the drug-loaded liposomes are coated on a stent along with a coating material free from any therapeutic substance. Rather, the liposomes of Golomb act as the coating layer itself.

Furthermore, there is no indication, nor even suggestion, that an additional coating material free from any therapeutic substance must necessarily be present on the stent in addition to the drug-delivery system. Thus, Golomb does not inherently anticipate claim 32 of the present invention.

For all the above reasons, the rejection of claims 25, 28-30 and 32 should be removed.

Additionally, claim 28 is independently patentable. Nowhere does Golomb disclose, either expressly or inherently, that the polymeric particles have a hydrogel consistency. Golomb does not disclose any of the polymeric materials used in the methods of the present invention rather simply discloses that the nanoparticles, preferably liposomes, can be prepared by methods known in the art. Thus, the materials and methods of Golomb would not necessarily result in a hydrogel consistency as required by

claim 28 of the application. Indeed, as disclosed in the present application, a hydrogel consistency depends on both materials and the manner of processing, e.g., dipping followed by spraying as disclosed on p. 17, lines 30-33 of the application.

Claim Rejections under 35 USC § 103(a)

Claims 25, 26, 28-30 and 32 have been rejected under 35 USC § 103(a) as obvious over Golomb. It is the position of the Examiner that since the drug-loaded compositions of Golomb are suitable for coating onto medical devices, the present invention, when taken as a whole, would have been *prima facie* obvious to one of ordinary skill in the art. This is not the case since Golomb fails to teach or suggest all the limitations of claims 25 and 32.

Applicants' Response

With respect to claim 25, nowhere does Golomb disclose, either expressly or inherently, drug-containing polymeric particles embedded within a coating layer on a stent.

In addition, nowhere does Golomb disclose, either expressly or inherently, that the coating layer includes an additional "...polymer different than the polymer from which the particles are made".

With respect to claim 32, nowhere does Golomb disclose, either expressly or inherently, a device coating free from any therapeutic substances but including particles of a polymeric material having a therapeutic substance added thereto.

Furthermore, the Examiner has provided no rationale for modifying the teachings of Golomb so that it teaches the above-mentioned limitations of claims 25 and 32. The key to supporting any rejection under 35 U.S.C. 103 is the clear articulation of the reason(s) why the claimed invention would have been obvious. Indeed, the Supreme Court states that "Rejections on obviousness cannot be sustained by mere conclusory statements; instead, there must be some articulated reasoning with some rational underpinning to support the legal conclusion of obviousness". *KSR International Co. v. Teleflex Inc.* (KSR) (550 U.S. ___, 82) (KSR). The Examiner, however, has failed to articulate why the teaching of Golomb could have been modified to teach the above

claimed limitations. Rather, the Examiner has merely concluded that the invention, “when taken as a whole”, would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made. The formulations of Golomb, however, are quite different from those of the present invention.

Golomb discloses agent-containing compositions that can be prepared as “...capsules, tablets, aerosols, solutions, suspensions or as a coating of a medical device such as a stent...” There is no teaching or suggestion that the coatings on such a medical device include capsules, tablets, aerosols, solutions or suspensions and an additional polymeric material or coating material, as required by claims 25 and 32 of the present invention. The present invention requires both therapeutic substance-containing polymer particles embedded in a coating layer and a coating layer that includes a polymer or material different from the polymer from which the particles are made. Indeed, the present invention includes a polymeric material, i.e., polymeric particle, inside of another polymeric material, i.e., the coating layer polymer, whereas Golomb simply teaches a single polymeric material on a device. A drug present in a coating on a stent of the present invention, therefore, has to travel through not only the polymeric particle, but also through the additional polymer or material present in the coating. The Examiner has not articulated why one skilled in the art would have looked to Golomb for guidance in teaching such a delivery system for the delivery of drug.

For all the above reasons, the rejection of claims 25, 28-30 and 32 should be withdrawn.

Additionally, claim 28 is independently patentable. Nowhere does Golomb disclose, either expressly or inherently, that the polymeric particles have a hydrogel consistency. Indeed, as disclosed in the present application, a hydrogel consistency depends on both materials and the manner of processing, e.g., dipping followed by spraying as disclosed on p. 17, lines 30-33 of the application.

Claims 27, 31 and 33 have been rejected under 35 USC § 103(a) as obvious over Golomb in view of U.S. Patent No. 6,379,379 to Wang. Wang discloses a stent coated with one or more polymer layers wherein the layers can optionally contain a drug and/or a radiochemical. It is the position of the Examiner that it would have been obvious to

one skilled in the art to combine the teachings of Wang with those of Golomb to obtain the invention as claimed. This is not the case since Wang does not remedy the deficiencies of Golomb.

Wang does not disclose, either expressly or inherently, drug-containing polymeric particles embedded within a coating layer on a stent. Furthermore, even if Wang suggested a drug-containing polymeric particle, which it does not, Wang does not disclose, either expressly or inherently, that the stent coating layer would include an additional "...polymer different than the polymer from which the particles are made". Therefore, one skilled in the art would not have been motivated to combine the teachings of Wang with Golomb so the rejection of claims 27 and 31 should be withdrawn. Claim 33 has been cancelled so this rejection is moot.

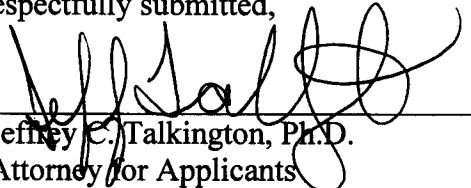
CONCLUSION

Removal of the rejections and allowance of the claims is respectfully requested. Should the Examiner have any questions or concerns, the Examiner is invited to call the undersigned attorney of record.

Date: February 20, 2008

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